

### **REMARKS**

Reconsideration of the present application, as amended, is respectfully requested.

### **TELEPHONE INTERVIEW**

Applicants' undersigned attorney appreciates the telephone interview that was conducted with the Examiner on October 31, 2007. During that interview, it was proposed that the limitations of claim 47 and/or 49 into-main claim 46. The Examiner indicated a willingness to consider such an amendment.

### **AMENDMENTS TO THE CLAIMS**

Claim 46 is amended to more particularly set forth the invention by including the elements of claim 47. This is done without prejudice to further prosecution of the pre-amendment scope of this claim. Claims 47, 48 and 50 are newly cancelled without prejudice. Claims 46, 49 and 55-70 are now pending.

### **THE CLAIMED INVENTION IS ENABLED UNDER 35 U.S.C. 112, FIRST PARAGRAPH**

At item 2 of the Office Action, claims 48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not enabled by the specification, as a new matter rejection. Claims 48 and 50 are cancelled, thus obviating this ground of rejection.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

### **THE CLAIMED INVENTION IS NOVEL UNDER 35 U.S.C. 102(b)**

At items 4-5 of the Office Action, claims 46, 50, 56 and 59 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Belsole (US 4,696,821).

Applicants respectfully disagree. Belsole describes a nitroglycerin water-soluble polyvinylpyrrolidone polymer film coated on one surface of aluminum foil and having an adhesive strip on the uncoated surface of the aluminum foil.

The Examiner did not reject claim 47 as allegedly anticipated by Belsole. Thus, it is respectfully submitted that claim 46, as amended to require the elements of claim 47, is fully

novel in view of Belsole for requiring one of the specific amounts of polyvinylpyrrolidone. Claims 50, 56 and 59 all depend from claim 46, thus obviating the instant rejection as to those claims, as well. In particular, it is urged that Applicants agree with the Examiner's conclusion that Belsole neither teaches or suggests the claimed delivery device, "wherein the polyvinyl pyrrolidone, is present in an amount, by dry weight, selected from the group consisting of 78 wt%, 80 wt%, 86 wt%, and 88.3 wt%."

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

At item 6 of the Office Action, claims 46, 55-60, 62, 64 and 66-68 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Biederman et al. (US 5,980,921; "Biederman").

Applicants respectfully disagree. The Examiner did not reject claim 47 as allegedly anticipated by Biederman. Thus, it is respectfully submitted that claim 46, as amended to require the elements of claim 47, is fully novel in view of Biederman. Claims 55-60, 62, 64 and 66-68 all depend from claim 46, thus obviating the instant rejection as to those claims, as well. In particular, it is urged that Applicants agree with the Examiner's conclusion that Biederman neither teaches or suggests. The claimed delivery device, "wherein the polyvinyl pyrrolidone, is present in an amount, by dry weight, selected from the group consisting of 78 wt%, 80 wt%, 86 wt%, and 88.3 wt%."

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### **THE CLAIMED INVENTION IS NONOBVIOUS UNDER 35 U.S.C. 103(a)**

At item 9 of the Office Action, claims 46, 49, 50 and 55-69 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Biederman et al. (as above). The Examiner seemingly takes the position that Biederman, taken alone, discloses the device of claim 46, et seq. and that it would have been obvious to apply the composition of Biederman to the skin in a single layer "with the expectation of uniform/efficient cleaning."

Applicants respectfully disagree. As noted for the rejection under 35 U.S.C. 102(b), *supra*, the Examiner did not reject claim 47 as allegedly rendered obvious by Biederman. Thus, it is respectfully submitted that claim 46, as amended to require the elements of claim 47, is nonobvious in view of Biederman. Claims 49, 50 and 55-69 all depend from claim 46, thus obviating the instant rejection as to those claims, as well. In particular, it is urged that

Applicants agree with the Examiner's conclusion that Biederman neither teaches or suggests the claimed delivery device, "wherein the polyvinyl pyrrolidone, is present in an amount, by dry weight, selected from the group consisting of 78 wt%, 80 wt%, 86 wt%, and 88.3 wt%."

In addition, given the particular formulation recited by claim 46, which is based on the particular features of the invention as exemplified, it is submitted that it would not have been obvious to apply the composition of Biederman to the skin in a single layer "with the expectation of uniform/efficient cleaning," for the particular specific percentages of polyvinyl pyrrolidone.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

At item 11 of the Office Action, claims 46 and 70 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Belsole (as above). The Examiner takes the position that Belsole teaches the composition of claim 46, but then concedes that, "Belsole is silent on the thickness of the film." However, the Examiner then takes the position that, "it would be obvious to one of ordinary skill in the art at the time of the invention to use a transdermal film having a desired thickness for application to the skin tissue to achieve the desired drug delivery."

Applicants respectfully disagree. As noted for the rejection under 35 U.S.C. 102(b), *supra*, the Examiner did not reject claim 47 as allegedly rendered obvious by Belsole. Thus, it is respectfully submitted that claim 46, as amended to require the elements of claim 47, is nonobvious in view of Belsole. Claim 70 depends from claim 46, thus obviating the instant rejection as to that claim, as well. In particular, it is urged that Applicants agree with the Examiner's conclusion that Belsole neither teaches or suggests the claimed delivery device, "wherein the polyvinyl pyrrolidone, is present in an amount, by dry weight, selected from the group consisting of 78 wt%, 80 wt%, 86 wt%, and 88.3 wt%."

In addition, given the particular formulation recited by claim 46, which is based on the particular features of the invention as exemplified, it is submitted that it would not have been obvious to use a transdermal film having a desired thickness for application to the skin tissue to achieve the desired drug delivery.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

At item 12 of the Office Action, claims 46,47 and 48 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Belsole (as above) in view of Yukimatsu et al. (US 4,740,365, "Yukimatsu"). The Examiner concedes that Belsole does not teach the percent amount of the

polyvinylpyrrolidone recited in claims 47 and 48. However, the Examiner then takes the position that,

it is known in the art to use polyethylene glycol and polyvinylpyrrolidone at percent amounts of 20-80% in carrier composition for nitroglycerin or nifedipine or isosorbide dinitrate (column 4, lines 56; column 6, lines 9-11, 58,59). Therefore, the ordinary skilled artisan, would have been able to use a combination of polyethylene glycol and 20-80% polyvinylpyrrolidone as the carrier composition for nitroglycerine according to the teaching of Yukimatsu.

Applicants respectfully disagree. Claim 46 as amended does not require a range of polyvinylpyrrolidone from 20-80%, as stated by the Examiner. Claim 46 presently requires that the “polyvinyl pyrrolidone, is present in an amount, by dry weight, selected from the group consisting of 78 wt%, 80 wt%, 86 wt%, and 88.3 wt%. This is a specificity not taught or suggested by Belsoe and/or Yukimatsu, taken in any combination. Thus, it is submitted that it would not have been obvious to use polyvinylpyrrolidone of 78 wt%, 80 wt%, 86 wt%, and 88.3 wt% as required by claim 46 and as exemplified by the specification.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

At item 13 of the Office Action, claims 46 and 61 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Belsole (as above), in view of Guittard et al. (US 4,576,604, “Guittard”). The Examiner concedes that Belsole does not teach using PEG 4000 in the composition, but alleges that Guittard would have provided this missing element of claim 61.

Applicants respectfully disagree. Belsoe fails to describe the invention for the reasons given above. Guittard fails to remedy this shortcoming, because this reference is submitted to represent a completely nonanalogous art reference. Guittard teaches an osmotic device that “comprises a wall surrounding a compartment containing an agent, a passageway in the wall connecting the exterior of the device with the compartment, and (a) an agent in the wall or (b) an agent carried on the wall in the wall. The device delivers the agent from the compartment and the wall,” as summarized by the Abstract.

It is urged that the ordinary artisan would not have looked to, or based any expectation of success, in combining a cardiac agent, such as nitroglycerin, with the elements of claim 46, et seq. based the mere listing of such an agent in Col. 15 of Guittard. The Examiner’s attention is respectfully directed to the detailed description of Guittard, of which Col. 15, line 20 is merely a one of the myriad of drugs that can be in Guittard’s osmotic solute (Col. 13, line 11, and Col. 13,

line 52, et seq.) In turn, the osmotic solute must be in the nonanalogous osmotic device, which has a completely nonanalogous structure, e.g., as described by Col. 7, line 45 through Col. 12, line 50.

### CONCLUSION

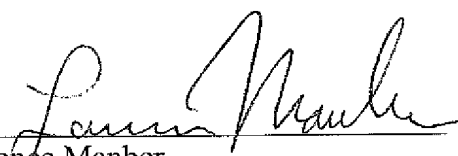
This response is being filed with a Petition for a one-month extension of time, and the required petition fee. No fee is believed to be due for additional claims. If, on the other hand, it is determined that any fees are due or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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